

FDA Risk Communication Advisory Committee
FDA White Oak Campus, 10903 New Hampshire Ave.
Bldg. 31, Conference Center (rm. 1503)
Silver Spring, MD

November 17, 2011 Discussion Topics

Note: Please note that the discussion in this notice will focus on promotional labeling and print advertising. The discussion will *not* include Patient Medication Information (PMI), which is provided to a patient only after he or she has been prescribed a medication. FDA is actively addressing PMI issues and these activities fall outside the scope of this meeting.

Session I: In Section 3507 of the Patient Protection and Affordable Care Act, Congress told FDA to review scientific evidence related to possible changes in advertising and promotional labeling (see below). The following questions relate to the scientific literature review.

1. Many relevant studies are designed to test simple examples whereas FDA faces a more complex world (for example, a study might test the effectiveness of pictographs by communicating information about one side effect whereas a real life drug may have ten side effects). Given this discrepancy, what gaps, if any, exist in the literature that need to be addressed before we can determine *whether* a standardized format (such as a table or drug facts box) and *what kind* of standardized format is appropriate in the promotional labeling or print advertising of such drugs to improve health care decision-making by clinicians, patients, and consumers?
2. Are there any data that would shed light on how to *select and present* information that would be most useful for improving health care decision-making by clinicians, patients, and consumers, for example in cases like these:
 - a. The clinical trial data available about a product comes not from just one study, but many studies that may differ in quality, methodology, and results
 - b. The product has several different indications (uses)
 - c. Products studied in different populations (for example, a drug may be studied in a population at risk for a disease whereas its competitor is studied in a population of people who have the disease)
 - d. The existing situation in which the effectiveness or benefit data available about different products comes from different types of endpoints, such as endpoints that are composites (for example, all-cause mortality), surrogate markers (for example, viral load), performance on a pre-developed standard test or scale (for example, the Brief Psychiatric Rating Scale), and other complex or technical endpoints (for example, progression-free survival)

- e. The warning or risk information about different products differs in severity and importance (for example, some drugs have boxed warnings and others do not)
 - f. The severity of the medical conditions that different products are indicated for vary and some medical conditions are symptomatic whereas others are asymptomatic
 - g. The target audiences for the information vary in their health literacy and numeracy and in the amount of detail they want
3. If no scientific evidence from the risk communication literature is available for some of the cases above, how can the FDA get a scientific basis for how information should appear in promotional labeling and advertising to improve health care decision making?
 4. Are there any additional topics that should be included in the literature review? If so, what are they?
 5. Are there any additional articles that should be included in the literature review? If so, what are they?

SEC. 3507. PRESENTATION OF PRESCRIPTION DRUG BENEFIT AND RISK INFORMATION.

IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”), acting through the Commissioner of Food and Drugs, shall determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decision making by clinicians and patients and consumers.

REVIEW AND CONSULTATION.—In making the determination under subsection (a), the Secretary shall review all available scientific evidence and research on decision making and social and cognitive psychology and consult with drug manufacturers, clinicians, patients and consumers, experts in health literacy, representatives of racial and ethnic minorities, and experts in women’s and pediatric health.

REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary shall submit to Congress a report that provides— (1) the determination by the Secretary under subsection (a); and (2) the reasoning and analysis underlying that determination.

(d) AUTHORITY.—If the Secretary determines under subsection (a) that the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decision making by clinicians and patients and consumers, then the Secretary, not later than 3 years after the date of submission of the report under subsection (c), shall promulgate proposed regulations as necessary to implement such format.

(e) CLARIFICATION.—Nothing in this section shall be construed to restrict the existing authorities of the Secretary with respect to benefit and risk information.

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